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EXAMINER	
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ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,020	NAGHAVI ET AL.	
	Examiner	Art Unit	
	NICHOLAS L. EVOY	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 42-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 42-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/10/10 and 10/22/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 42-77, drawn to a method for difference imaging.

Group II, claim(s) 78-87, drawn to a catheter apparatus.

2. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

3. Group I is directed to methods that require a pre-alteration step and a post-alteration step with specific limitations directed to a intra-vessel balloon. Group II is directed to a generic catheter apparatus configured for use inside an animal or human vessel. The invention of Group II could be used for any catheter process and in no way is limited to the method of Group I.

4. During a telephone conversation with Bruce Black on 10/18/10 a provisional election was made without traverse to prosecute the invention of Group I, claims 1 and 42-77. Affirmation of this election must be made by applicant in replying to this Office action. Claims 78-87 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result**

in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Objections

7. Claim 47 objected to because of the following informalities: the word “supply” is grammatically incorrect. For the purposes of examination, the term is interpreted to mean "supplying". Appropriate correction is required.

8. Claim 55 objected to because of the following informalities: the word “an” is grammatically incorrect. For the purposes of examination, the term is interpreted to mean “and”. Appropriate correction is required.

9. Claims 73-74 objected to because of the following informalities: the word “contract” is grammatically incorrect. For the purposes of examination, the term is interpreted to mean “contrast”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1 and 42-77 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Regarding claims 1 and 75, in line 2, the claims recite "…adjacent a tissue site of an animal including a human" which is vague and indefinite. For the purposes of examination, the claim is interpreted to read "...adjacent a tissue site of an animal or a human". Claims 42-74 and 76-77 are rejected as being dependent on independent claims 1 and 75.

13. Regarding claims 53-58, the terms "pre phase-correlated data" and "post phase-correlated data" are vague and indefinite. For the purposes of examination, the terms are interpreted to mean "phase-correlated data from the pre-injection data" and "phase-correlated data from the post-injection data".

14. Regarding claim 74, the term "the site" lacks antecedent basis in the claim. Independent claim 1 recites a "tissue site" and an "injection site", but no reference is made to "the site". For the purposes of examination, "the site" is interpreted to mean "either the tissue site or the injection site".

15. Regarding claim 75, the terms "pre-altered blood flow data", "during-altered blood flow data" and "post-altered blood flow data" are vague and indefinite. For the purposes of examination, the terms are interpreted to mean "blood flow data prior to an alteration", "blood flow data during an alteration" and "blood flow data after an alteration".

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 1, 42-54, 59-60, 62, 71-72 and 75-77 rejected under 35 U.S.C. 102(b) as being anticipated by Young, US Patent Number 6,219,572 B1.

18. Regarding claim 1, Young discloses a method comprising the steps of : positioning a probe adjacent a tissue site of an animal including a human; acquiring pre-injection data of the tissue site; injecting a contrast agent into the animal at an injection site; acquiring post-injection data of the tissue site; performing a difference analysis between pre-injection data and post0injection data to detect, localize, and quantify anatomical, morphological and/or functional features of the tissue site (Column 1, Line 55 – Column 2, Line 36).

19. Regarding claim 42, Young discloses the method of claim 1, further comprising the steps of: prior to the injecting step, positioning a contrast agent delivery system adjacent the injection site (Column 3, Lines 3-24).

20. Regarding clam 43, Young discloses the method of claim 1, wherein the pre-injection data comprises a pre-injection data sequence of the tissue site acquired over a pre-injection period of time (Column 1, Line 56 – Column 2, Line 36).

21. Regarding claim 44, Young discloses the method of claim 1, wherein the post-injection data comprises a post-injection data sequence of the tissue site acquired over a post-injection period of time (Column 1, Line 56 – Column 2, Line 36).

22. Regarding claim 45, Young discloses the method of claim 1, wherein the difference analysis is between the pre-injection data sequence and post-injection data sequence (Column 3, Lines 25-60).

23. Regarding claim 46, Young discloses the method of claim 1, wherein the injection site comprises a vessel (Column 1, Lines 56-65).

24. Regarding claim 47, Young discloses the method of claim 46, wherein the vessel comprises an artery supply blood to the tissue site or a vein removing blood from the tissue site (Column 1, Lines 56-65).

25. Regarding claim 48, Young discloses the method of claim 46, wherein the tissue site is a vessel and the step of positioning the probe comprises the steps of: positioning a guide-catheter in the vessel; and positioning, on the guide-catheter, a micro-catheter including the probe in the vessel adjacent the tissue site (i.e. catheter and injector and tube, Column 3, Lines 3-24).

26. Regarding claim 49, Young discloses the method of claim 1, further including the step of: acquiring during injection data sequence, wherein the performing step further includes difference analyses of the pre-injection, during-injection and post-injection data sequences (Column 3, Lines 25-60).

27. Regarding claim 50, Young discloses the method of claim 1, wherein the data comprises ultrasonic data (Column 3, Lines 50-53).

28. Regarding claim 51, Young discloses the method of claim 49, wherein the data comprises ultrasonic data (Column 3, Lines 50-53).

29. Regarding claim 52, Young discloses the method of claim 1, wherein the pre-injection data comprises a pre-injection data sequence of the tissue site acquired over a pre-injection period of time and the post-injection data comprises a post-injection data sequence of the tissue site acquired over a post-injection period of time (Column 1, Line 56 – Column 2, Line 36).

30. Regarding claim 53, Young discloses the method of claim 52, further comprising the step of: forming pre phase-correlated data from the pre-injection data and post phase-correlated data from the post-injection data (i.e. phase-correlated data from a phase-correlated imaging process such as MRI or ultrasound, Column 1, Line 56 - Column 2, Line 36).

31. Regarding claim 54, Young discloses the method of claim 53, further comprising the step of: selecting a region of interest within the pre and post phase-correlated data (Column 1, Lines 29-34).

32. Regarding claim 59, Young discloses the method of claim 52, wherein the data acquisition times are from about .5 minutes to about 30 minutes (Column 1, Lines 6-11).

33. Regarding claim 60, Young discloses the method of claim 52, wherein the pre-injection data is acquired over a pre-injection period of time ranging from about 1 second to about 10 minutes and the post-injection data is acquired over a post-injection period of time ranging from about 1 second to about 20 minutes (Column 1, Lines 6-11).

34. Regarding claim 62, Young discloses the method of claim 1, further comprising the step of: generating difference data or image sequences between data or frames in the pre- and post- injection data (Column 1, Line 56 – Column 2, Line 36).

35. Regarding claim 71, Young discloses the method of claim 1, wherein the probe is selected form the group consisting of an ultrasound probe, a variable frequency ultrasound probe, a magnetic probe, a photonic probe, a near infrared probe, a terahertz probe, microwave probe and combinations thereof (i.e. ultrasound, Column 3, Lines 50-53).

36. Regarding claim 72, Young discloses the method of claim 1, wherein the contrast agent is selected from the group consisting of microbubbles, magnetically active microbubbles, magnetically active nanoparticles, near Infrared visible microbubbles, near Infrared visible nanoparticles, optically visible microbubbles, optically visible nanoparticles, terrahertz visible microbubbles, terrahertz visible nanoparticles, microwave visible microbubbles, microwave visible nanoparticles, red blood, cells including magnetically active nanoparticles, near Infrared visible nanoparticles, optically visible nanoparticles, terrahertz visible nanoparticles, microwave visible nanoparticles, and mixtures thereof, and mixtures or combinations thereof (Column 1, Lines 27-28).

37. Regarding claim 75, Young discloses a method comprising the steps of: positioning a probe adjacent a tissue site of an animal including a human, acquiring pre-altered blood flow data of the tissue site, positioning a balloon in an artery supplying blood to or a vein removing blood from the tissue site, altering a blood flow to the tissue site by inflating or partially inflating the balloon, acquiring during-altered blood flow data of the tissue site, deflating the balloon, acquiring post-altered blood flow data of the tissue site, performing a difference analysis between pre-altered blood flow data, during-altered blood flow data and post-altered blood flow data to detect, localize, and

quantify anatomical, morphological and/or functional features of the tissue site (Column 1, Lines 55 - Column 2, Lines 36 and Column 3, Lines 25-60).

38. Regarding claim 76, Young discloses the method of claim 75, wherein the inflating and deflating steps are performed periodically at a given periodicity (Column 3, Lines 3-11).

39. Regarding claim 77, Young discloses the method of claim 75, wherein red blood cells act as a contrast agent (Column 3, Lines 12-24).

Claim Rejections - 35 USC § 103

40. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

41. Claims 55-58 and 73-74 rejected under 35 U.S.C. 103(a) as being unpatentable over Young, US Patent Number 6,219,572 B1, in view of Rafter et al, US PG Pub Number 2003/0163048 A1.

42. Regarding claims 55-58, Young teaches a method as referenced above. Young does not teach the step of compensating for motion within the region of interest in the dataset. Rafter teaches an ultrasonic imaging method to detect coronary artery stenosis at rest. Rafter specifically discloses a substep of employing motion compensation techniques within a region of interest to improve visualization of the arterioles and remove imaging artifacts caused by the pulsitile nature of blood flow (Paragraph [0054]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include the step of compensating for motion within the region of interest in the data set in the invention of Young because it is well known in the art that bodies in general, and more specifically organs and vessels (as is disclosed in Rafter) are not completely stationary and that compensating for motion would be an obvious step to avoid blurred and distorted imaging data (Paragraph [0054]).

43. Regarding claim 73-74, Young teaches a method as referenced above. Young does not teach the step of exposing the tissue to a sonic energy at a frequency sufficient to destroy contrast agent. Rafter teaches a method as referenced above, with the additional step of destroying microbubbles in the arterioles and capillaries using high power ultrasonic energy (Abstract and Paragraphs [0013]-[0014]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of exposing the tissue to a sonic energy at a frequency sufficient to destroy contrast agent to Young because process of rupturing microbubbles allows for a user to obtain a more optimal concentration of microbubbles in the vessel for contrast imaging (Paragraphs [0028]-[0031]).

44. Claims 61 and 63-70 rejected under 35 U.S.C. 103(a) as being unpatentable over Young, US Patent Number 6,219,572 B1, in view of O'Donnell et al, US Patent Number 5,921,931.

45. Regarding claims 61 and 63-70, Young teaches a method as referenced above. Young does not teach the steps of temporally sorting data, performing noise reduction and color-coding.

46. O'Donnell teaches a method and apparatus for creating a color blood flow image based upon ultrasonic echo signals received by an intravascular ultrasound imaging probe with the specific features of threshold noise reduction (Column 4, Lines 5-22) and binning of data values for color-coding (Column 9, Lines 4-63).

47. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Young and O'Donnell because both inventions are directed to two-phase medical imaging methods and the invention of O'Donnell is "particularly directed to displaying an image rendered by the ultrasound imaging system of the dynamic portions of the field of view in various ones of multiple colors associated with varying degrees of dynamic behavior, and wherein the colorized dynamic image is superimposed upon an image of relatively static features represented in gray scale format" (Column 1, Lines 29-40).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICHOLAS L. EVOY whose telephone number is (571)270-1388. The examiner can normally be reached on M-F 7:30-5:00, Alternating Fridays Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NICHOLAS L. EVOY/
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768